Controlled Substance Research Policy

Policy 303.28

1 Purpose

1.1 The purpose of this policy is to outline the rules and regulations surrounding Controlled Substances as they are used in research.

2 Scope

2.1 This policy shall apply to any and all persons seeking to obtain or use Controlled Substances in research for Appalachian State University or on Appalachian State University property.

3 Definitions

3.1 Controlled substances

Any drugs or chemical substances whose possession and use are regulated under the United States Controlled Substances Act, or the North Carolina Controlled Substances Act. The U.S. Department of Justice, Drug Enforcement Administration (DEA) administers the federal law, and the North Carolina Department of Health and Human Services (DHHS), Drug Control Unit administers the state law. Controlled substances have stimulant, depressant, or hallucinogenic effects on the higher functions of the central nervous system and tend to promote abuse or physiological/psychological dependence. An alphabetical list is included here.

3.2 Substance Schedules

Substances regulated under the U.S. Controlled Substances Act (CSA) are in one of five schedules. Schedule I substances have the most restrictions, and Schedule V substances the least. The CSA defines the schedules as follows:

- Schedule I: Drug or other substance with a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety protocols for use under medical supervision.
- Schedule II: High potential for abuse; a currently accepted use in treatment in the United States, or currently accepted medical use with severe restrictions; abuse may lead to severe psychological or physical dependence.
- Schedule III: Potential for abuse less than Schedule I or II substances; currently accepted medical use in treatment in the United States; abuse may lead to moderate or low physical dependence or high psychological dependence.
- Schedule IV: Low potential for abuse relative to Schedule III; currently accepted medical use in treatment in the United States; abuse may lead to limited physical or psychological dependence relative to Schedule III.
- Schedule V: Low potential for abuse relative to Schedule IV; currently accepted medical use in treatment in the United States; abuse may lead to limited physical or psychological dependence relative to Schedule IV.

3.3 NC Controlled Substance Act

North Carolina General Statute Chapter 90 Article 5

3.4 Practitioner

A physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

4 Policy Statements

4.1 Registration and Acquisition

4.1.1 Only registered personnel with the appropriate state and federal licenses may order controlled substances. Individual registration and licensing is required for use of Schedule I controlled substances without exception. Prior to ordering controlled substances, researchers shall be required to receive three approvals: institutional approval, state approval, and federal approval.

4.1.2 Institutional Approval

4.1.2.1 A Letter of Institutional Approval is required for State and Federal approval. Applicants seeking a Letter of Institution Approval shall:

1. Register to obtain controlled substances through the office of Environmental Health and Safety and Emergency Management using the Controlled Substances Registration Form.
2. Complete and sign a Use Agreement with the University
3. Meet with the Industrial Hygiene Manager
4. Prepare a Research Protocol subject to 21 CFR 1301.18

4.1.2.2 Controlled Substance Research Advisory Board: A Controlled Substance Research Advisory Board shall be established and consist of members including: Faculty, Staff, Office of Research, General Counsel, App State PD, and Environmental Health, Safety, & Emergency Management. The Controlled Substance Research Advisory Board shall:

1. Review applications seeking a Letter of Institutional Approval for Controlled Substances.
2. Make a recommendation to grant or deny application to the Vice Provost for Research and Director or Environmental Health and Safety and Emergency Management.
3. Determine frequency of lab safety reviews.
4. Review any laboratory safety non-compliance.

4.1.2.3 Letter of Institutional Approval: A Letter of Institutional Approval may only be granted by the Vice Provost for Research and Director of Environmental Health and Safety and Emergency Management upon recommendation by the Controlled Substance Research Advisory Board.

4.1.3 State Approval: State Approval shall be dictated by the NC Department of Health and Human Services.

4.1.4 Federal Approval: Federal Approval shall be dictated by the Drug Enforcement Agency.

4.2 Security

4.2.1 The registrant is responsible for managing all controlled substances in accordance with all regulatory requirements including security, inventory, and recordkeeping.

4.2.2 Facility Security

4.2.2.1 Regardless of schedule, all controlled substances must be kept under lock and key, in a substantially constructed cabinet or safe, and accessible only to authorized personnel. Storage cabinets must be heavy enough to be essentially immovable or built into the structure of the building. Doors must not be prone to forced opening by prying tools, or easily removable at the hinges. Wood or laminate casework is not likely to provide adequate security. The storage location must be approved by EHS & EM.
4.2.2.2 Thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must be stored in a safe or steel cabinet equivalent to US Gov Class V security container. The storage container must be approved by EHS & EM.
4.2.2.3 All controlled substances must be locked in their storage locations except for the time required for authorized staff to remove, work with, and replace them.
4.2.2.4 The storage area must be protected by an alarm system that is continuously monitored by an alarm company central station.
4.2.2.5 The Code of Federal Regulations dictates separate requirements for practitioners who are researchers and analytical laboratory personnel versus practitioners who are physicians, dentists, veterinarians, pharmacies or hospitals. It is the responsibility of the applicant to ensure compliance with all Federal rules and regulations regarding security.

4.2.3 Personnel Security

4.2.3.1 The registrant may authorize additional personnel to use the substances for approved activities. The registrant is required to screen these personnel prior to authorization, using the following questions for non-practitioners who seek access to DEA controlled substances (ref. 21 CFR 1301.90):

- Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or are you presently charged with committing a criminal offense?
- In the past three years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?
- Have you had an application for registration with the DEA denied, revoked, or surrendered for cause?

An affirmative answer to any of the three questions above requires review by the Controlled Substances Research Advisory Board to determine if the personnel should have access to the controlled substances. Registrants must maintain the answers to these screening questions for authorized personnel in a secure place, away from the purview of

unauthorized personnel. A sample form is included here.
4.2.3.2 Schedule I substances may not be issued to anyone other than the registrant or used in a retrievable form by anyone other than the registrant. If additional personnel need to use Schedule I substances, they must individually register with NC-DHHS, Drug Control Unit and DEA.

4.3 Inventory and Recordkeeping

4.3.1 Registrants must maintain complete and accurate inventory records for all controlled substances. These records must be in or near the primary work area, separate from all other records and documents, and available for inspection during regular work hours.

4.3.2 Records must include at least the following information:

1. **Receipt of Controlled Substance:** A separate and current record indicating the date received, name and address of supplier, the type, strength, and concentration of substance, and the amount received. The person receiving the substance must sign each record.
2. **Use of Controlled Substance:** A separate and current record for the storage and use of each controlled substance, indicating the starting quantity, use date, building and room, specific research experiment or analysis, type and strength used, and the quantity used. Each use is a subtraction from the starting quantity, and the running amount must equal the total amount remaining. The person working with the substance must sign each record of use. A sample form is included here.
3. **Inventory of Controlled Substance:** In addition to the balance log records, initial and biennial inventory records are required for Schedule I and II substances. These shall include the name of each substance, each finished form of the substance (solid, tincture, inhalant, etc.), the number of units or volume of each finished form, and the number of containers of each finished form. Damaged, defective, expired, or impure substances awaiting disposal must be included in the inventory until they are disposed of. A sample form is included here.
4. **Labeling of Controlled Substances:** All containers of controlled substances must be individually identified by the following information:
    1. The name and schedule of the controlled substance.
    2. The lot number (or tracking number) of the product. (This is unique and not a reusable number).
    3. The date reconstituted (powders) or combined with other substrates.
    4. The final concentration.
    5. The quantity of the controlled substance(s) per container.
    6. The expiration date (per manufacturer or most recent date of combined substance).
    7. The name of the Registrant for the controlled substance.

    The original packaging for the controlled substance(s) should be utilized whenever possible. Containers (i.e., vials, ampoules) may be removed from the original packaging if the marking on the exterior of the vials or ampoules provide the above information or can be added to the container as appropriate.
5. **Recording Waste Disposal:** Any controlled substances that are declared unwanted product or expired must be destroyed and rendered irretrievable prior to disposal as a chemical waste. Controlled substance destructions must be completed by the registrant. The registrant must contact a Drug Control Inspector (DCI) at the North Carolina Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services (919-733-1765) in order to have the DCI witness the destruction of any unwanted or expired controlled substances in accordance with NC law. The registrant must also contact the University EHS&EM Department Environmental Affairs Manager and the Industrial Hygiene Manager prior to destroying the controlled substance in order to arrange for the disposal of the chemical waste and for the provision of destruction materials. Each controlled substance destruction and disposal must be witnessed by EHS&EM in addition to the NC DCI agent regardless of quantity. The registrant and NC DCI witness must sign appropriate DEA forms confirming the date of the destruction and subsequent disposal of the waste of the controlled substances involved. The registrant must then provide the completed DEA forms to the DEA Office of Diversion Control Agent; a copy of the DEA forms must also be transmitted to the EHS&EM Environmental Affairs Manager and the Industrial Hygiene Manager.

4.3.3 If the registrant is not available to perform the destruction (for example, the registrant has left the institution, or is deceased), the laboratory manager must contact the NC-DHHS, Drug Control Unit or DEA Diversion Control at 336-547-4219 EHS&EM Environmental Affairs Manager and the Industrial Hygiene Manager to arrange for an official to witness the destruction of the controlled substance(s) prior to disposal. Security for any found controlled substance(s) must follow all requirements of this document as well as any applicable state and federal regulation.

4.3.4 The registrant must maintain all of the above-referenced records for a period of at least three years from the date of the last entry. In the event of an audit by DEA or NC-DHHS, Drug Control Unit, the registrant must be able to produce these records.

4.4 Loss, Theft, or Misuse

4.4.1 In the event that controlled substances are lost, stolen, or used in an unauthorized manner, the registrant must immediately contact the App State Police at 828-262-8000 (or 911), and the DEA Office of Diversion Control in Greensboro,

phone number 336-547-4219. The DEA staff will let you know whether you need to fill out a copy of DEA Form 106: Report of Theft or Loss of Controlled Substances. Complete appropriate online forms and submit electronically via the internet to DEA Headquarters. Instructions for completing the form are online.

4.5 Disposal

4.5.1 The registrant must account for all controlled substances prior to their destruction and disposal. The registrant must document the destruction of all controlled substances as per this document. Prior to any destruction, state law mandates that the DHHS Drug Control Inspector must be present for all controlled substance waste destruction in order to witness and document all destructions. All controlled substances shall be destroyed and disposed of by the one of the following methods:

1. **Waste/Contaminated Product'** (e.g., unused part of injection or ampule, or residue in original container): In cases where small amounts of controlled substances are left over from an experiment or procedure, the registrant may properly dispose of the unused materials according to methods below:
    1. Residue Powders: Mix powders with a liquid (e.g., Drug Buster®, bleach or other disinfectant) ensuring that the mixture is depleted of solids. Next, pour this new liquid onto absorbent material (e.g., soda-sorb, kitty litter) and contact the EHS&EM Environmental Affairs Manager for incineration disposal.
    2. Liquids: Pour onto absorbent material (e.g., soda-sorb, kitty litter) and contact the EHS&EM Environmental Affairs Manager as described above for proper disposal methods.
    3. Empty Bottles: Deface the label entirely and throw in sharps container for incineration or in container with absorbent material for incineration. Bottles with excess powder can be rinsed with a liquid (e.g., bleach or other disinfectant). All liquids must be placed onto absorbent material and disposed of as described above.
    4. Patches: Cut into small pieces and place in sharps container for incineration or use Drug Buster, ensuring that the mixture is depleted of solids. Next, pour this new liquid onto absorbent material (e.g., soda-sorb, kitty litter) to render irretrievable and contact the EHS&EM Environmental Affairs Manager for incineration and disposal.
    5. Syringe: Inject materials onto absorbent material (e.g., soda-sorb, kitty litter) and contact the EHS&EM Environmental Affairs Manager as described above for proper disposal methods.

    :Note: Do not place any substances down the sink drain. Drug Buster®, kitty litter, and disposal containers can be provided by EHS&EM upon request. All expired drugs can be stored for disposal as long as they are clearly labeled, “expired” AND segregated (e.g., Ziploc® bag) from all unexpired product. Record these trace amounts in your disposition record as waste.
2. **Expired/Unwanted Product** (e.g., >0.5 ml or mg by volume in leftover multiuse vials or bulk powder containers, unused tablets, capsules, ampules, or vials): In cases where product is unwanted or expired, registrants must contact NC-DHHS AND EHS&EM representatives to schedule controlled substance destruction. If large quantities of controlled substances are identified, (e.g. abandonment or retirement), registrants may also need to contact a DEA certified reverse distributor to arrange for reverse disposal. Because this list changes due to registration requirements, please contact NC-DHHS, Drug Control Unit at 919-733-1765 or DEA Diversion Control at 336-547-4219 for approved vendors.
3. **Controlled Substances Found on Campus with No Registrant:**
    1. Secure any controlled substances by locking them in your controlled substances cabinet, lockable safe or desk drawer. Contact the Department Chair and the EHS&EM Environmental Affairs Manager (919-962-5509) to make them aware of the found substance.
    2. Contact the local DEA agent to arrange for a witness to the destruction of the found controlled substance(s). Please document this communication and contact the EHS&EM Environmental Affairs Manager (919-962-5509) for help and any additional instruction.

5 Additional References

1. Controlled Substances Registration Form
2. Controlled Substances – Alphabetical Order
3. Questionnaire for Personnel who will have Access to Substances Regulated by the U.S. Drug Enforcement Administration
4. Continuing Record for Acquisition and Disposition of Controlled Substances
5. Inventory of Controlled Substances
6. Controlled Substances Use Agreement Form

6 Administrative Unit Contacts

Environmental Health, Safety, and Emergency Management | 828-262-4008 | Environmental Health, Safety, and Emergency Management
Office of Research | 828-262-7459 | Office of Research